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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/125,022    11/24/98    DE FLORA    S    P8903-8035

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HM22/0926

EXAMINER

OWENS JR, H

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

09/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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# Office Action Summary

Application No.  
09/125,022

Applicant(s)  
De Flora et al.

Examiner  
Howard Owens

Group Art Unit  
1623

☒ Responsive to communication(s) filed on Feb 4, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 13-15 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 13-15 is/are rejected:

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

5 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

15 Claims 10 - 12 have been canceled. Therefore, only claims 13 - 15 are pending in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Objection to the specification**

20 Page 5, line 23 of the specification appears to contain the misspelled term "colture".

**35 U.S.C. 102(b)**

25 Claims 13 - 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Myers, Jr. et al. or Doroshov et al. or Meyers et al. or Freeman et al. for the reasons already of record on pages 2 - 4 of the Office action mailed 2-25-99.

30 The claims are directed to a method for inhibiting cancer metastasis formation in a host comprising the administration of a synergistically effective amount of N-acetylcysteine and doxorubicin. Claim 14 specifies that the dosage of N-acetylcysteine be between 100 mg and 6g/day. Claim 15 requires that the doxorubicin be administered in an amount of between 1 and 50 mg per dose.

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Each of above references discloses the use of doxorubicin and N-acetylcysteine in the treatment of cancer in the dosage ranges that overlap with applicant's ranges. Unlike the applicant, these references use N-acetylcysteine to reduce the cardiotoxicity of the doxorubicin. However, because the dosage ranges of both doxorubicin and N-acetylcysteine claimed by applicant and used in the prior art overlap, the instantly claimed method for inhibiting cancer metastasis formation is inherent in the prior art method for treating cancer comprising administering doxorubicin and N-acetylcysteine, even though the N-acetylcysteine is being used to prevent cardiotoxicity of the doxorubicin.

Another way to understand the inherency of applicant's invention is to grasp the unsolvable nature of the infringement problem applicant would encounter if, in fact, he were awarded a patent to claims 13 - 15. How could the applicant determine if his patent were being infringed by persons who were using doxorubicin and N-acetylcysteine to treat cancer in a patient using the same dosages as applicant's claims? Since the actual physical steps of the potential infringer and those of applicant's claims are indistinguishable, the only way to know if there were, in fact, infringement, would be to discern the mental processes of the person performing the steps. When the only difference between a prior art process and that of a claimed method is the state of mind of the person performing the task, then the prior art process must inherently meet the limitations of the instant claims.

Applicant has argued in the response filed 2-4-00 that since the instant claims are drawn to inhibiting cancer metastasis, the claims are not anticipated by the prior art of record which applicant asserts that the references only teach the treatment of solid tumors and not metastasis. Applicant's attention should be drawn to Doroshov et al. wherein it is taught (introduction, paragraph I) that "doxorubicin is an antineoplastic antibiotic that is now part of standard chemotherapeutic regimens for most hematopoietic malignancies as well as for advanced solid tumors of the breast, ovary, thyroid and bone". One of ordinary skill in the art would be provided with a reasonable

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expectation of success that an antimalignant agent would be useful in the treatment of metastasis; thus, applicant's arguments are not convincing and the rejection of record is maintained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

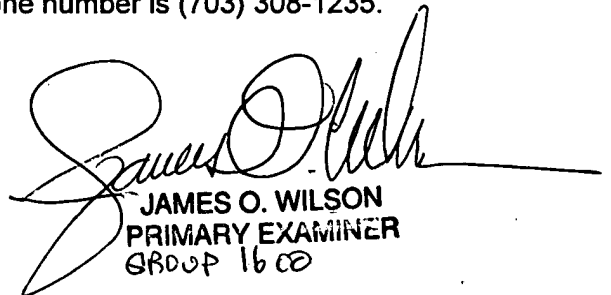
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Howard Owens  
Group 1623

  
**JAMES O. WILSON**  
**PRIMARY EXAMINER**  
**GROUP 1623**